



## ENZYMATIC THERAPY

INCORPORATED

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### INTEGRATIVE THERAPEUTICS INC.™

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Wilsonville, OR 97070

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### ENZYMATIC THERAPY™

&  
**PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 • F: 888.570.6460 (Enzymatic)

P: 920.469.9099 • F: 920.469.4418 (Phyto)

November 3, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
BP Manager™	The natural way to support healthy blood pressure* Maintain healthy blood pressure levels that are already within the normal range.*	Proprietary Phytotensive Blend – stevia (Stevia rebaudiana) leaf extract, olive (Olea europaea) leaf extract, hawthorn (Crataegus oxyacantha) leaf and flower extract, dandelion (Taraxacum officinale) leaf, Lycopene

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

11/3/04

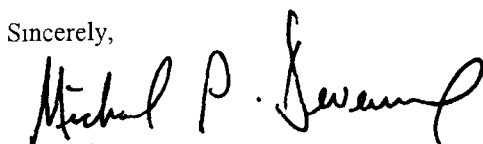
975 0162

LET

15016

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" and last name "Devereux" clearly legible, and "P." in the middle.

Michael P. Devereux  
Chief Financial Officer



## ENZYMATIC THERAPY

THE DIFFERENCE

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&  
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P: 920.469.1313 • F: 888.570.6460 (Enzymatic)  
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November 4, 2004

Office of Nutritional Products, Labeling &  
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Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
BP Manager™	Take control with BP Manager™! Your first step for maintaining healthy blood pressure, naturally.* BP Manager's clinically studied ingredients have been shown to be helpful for maintaining blood pressure levels that are already within the normal range.*	Proprietary Phytotensive Blend – stevia (Stevia rebaudiana) leaf extract, olive (Olea europaea) leaf extract, hawthorn (Crataegus oxyacantha) leaf and flower extract, dandelion (Taraxacum officinale) leaf, Lycopene

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By: 

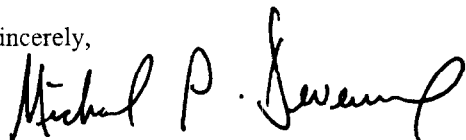
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/4/04

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Michael P. Devereux  
Chief Financial Officer



## ENZYMATIC THERAPY

NOT A PRODUCT

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
BP Manager™	Supporting healthy Blood Pressure can be a delicate balance, so BP Manager™ was developed to address many of the factors that affect blood pressure levels in your body.* BP Manager's clinically studied ingredients have been shown to be helpful for maintaining blood pressure levels that are already within the normal range.*	Proprietary Phytotensive Blend – stevia (Stevia rebaudiana) leaf extract, olive (Olea europaea) leaf extract, hawthorn (Crataegus oxyacantha) leaf and flower extract, dandelion (Taraxacum officinale) leaf, Lycopene

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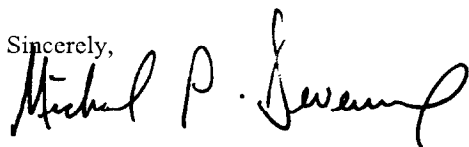
Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

11-4-04

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Michael P. Devereux  
Chief Financial Officer



## ENZYMATIC THERAPY

INTERNATIONAL

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November 5, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
BP Manager™	The clinically studied ingredients in this vegetarian formula support heart and circulatory health.*	Proprietary Phytotensive Blend – stevia (Stevia rebaudiana) leaf extract, olive (Olea europaea) leaf extract, hawthorn (Crataegus oxyacantha) leaf and flower extract, dandelion (Taraxacum officinale) leaf, Lycopene

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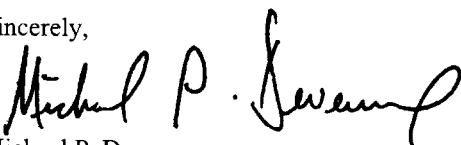
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 11-5-04

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Chief Financial Officer





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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
BP Manager™	BP Manager's proprietary herbal blend works in harmony with your body to support your blood pressure in natural and healthy ways.* BP Manager's clinically studied ingredients have been shown to be helpful for maintaining blood pressure levels that are already within the normal range.*	Proprietary Phytotensive Blend – stevia (Stevia rebaudiana) leaf extract, olive (Olea europaea) leaf extract, hawthorn (Crataegus oxyacantha) leaf and flower extract, dandelion (Taraxacum officinale) leaf, Lycopene

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By: \_\_\_\_\_

Robert C. Doster

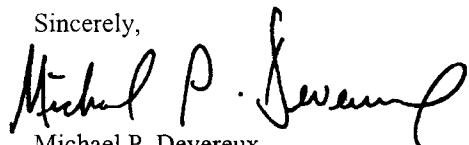
Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

11-5-04

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Michael P. Devereux  
Chief Financial Officer



## ENZYMATIC THERAPY

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November 5, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
BP Manager™	Supports healthy blood pressure levels according to clinical studies* BP Manager's clinically studied ingredients have been shown to be helpful for maintaining blood pressure levels that are already within the normal range.*	Stevia (Stevia rebaudiana) leaf extract

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By: Robert C. Doster

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/5/04

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NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

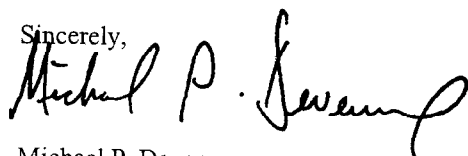
9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 F: 503.582.0467

**ENZYMATIC THERAPY®**  
&  
**PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
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November 5, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
BP Manager™	Supports the heart and balances sodium and fluid levels.*	Hawthorn (Crataegus oxycantha) leaf and flower extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

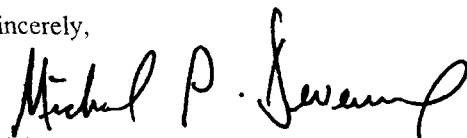
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 11-5-04

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Michael P. Devereux  
Chief Financial Officer



## ENZYMATIC THERAPY

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November 5, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
BP Manager™	Scientifically shown to support healthy blood pressure.* BP Manager's clinically studied ingredients have been shown to be helpful for maintaining blood pressure levels that are already within the normal range.*	Olive (Olea europaea) leaf extract

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By: 

Robert C. Doster

Title Senior Vice President of Scientific Affairs

Date: 11-5-04

### INTEGRATIVE THERAPEUTICS INC.™

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### PHYTOPHARMICA®

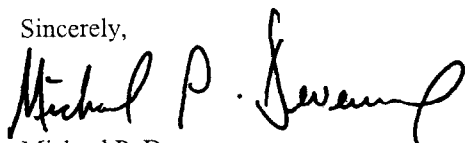
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November 6, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
BP Manager™	A source of potassium that helps reduce fluid retention*	Dandelion (Taraxacum officinale) leaf

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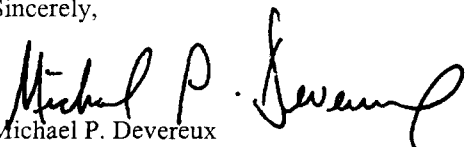
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Title: Senior Vice President of Scientific Affairs

Date: 11-6-04

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
BP Manager™	Clinically shown to support arteries, circulation and heart health*	Lycopene

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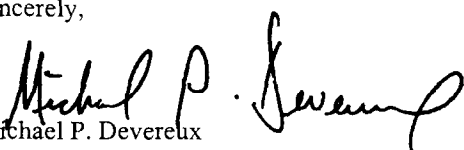
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Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
BP Manager™	Supports heart health*	Proprietary Phytotensive Blend – stevia (Stevia rebaudiana) leaf extract, olive (Olea europaea) leaf extract, hawthorn (Crataegus oxyacantha) leaf and flower extract, dandelion (Taraxacum officinale) leaf, Lycopene

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

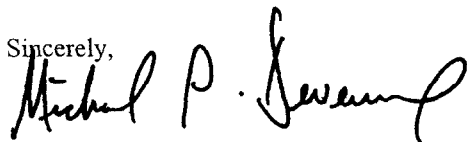
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 11-6-04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux  
Chief Financial Officer